

**Health Information Technology Standards Committee
Final
Summary of the March 29, 2011, Meeting**

KEY TOPICS

1. Call to Order

Judy Sparrow, Office of the National Coordinator (ONC), welcomed participants the 23rd meeting of the HIT Standards Committee (HITSC). She reminded the participants that this was a Federal Advisory Committee meeting, with an opportunity for the public to make comments, and that a transcript of the meeting would be available online. She conducted roll call, and turned the meeting over to Acting National Coordinator for Health Information Technology Farzad Mostashari.

2. Opening Remarks

Mostashari acknowledged that the outgoing National Coordinator for HIT, David Blumenthal, helped to create a legacy in the past 2 years with the design and launch of the programs and policies that came out of the Health Information Technology for Economic and Clinical Health (HITECH) Act. As this group moves from strategy to execution on many of the things they have started, they must try to stay consistent with the principles of openness and transparency in their work. They must also be bold and ambitious, knowing that they are striving for improved health and health care, not for technology as an end in itself. Most importantly, they must put the patient's interests first in everything they do.

Mostashari commented that there is a tremendous amount of work for this Committee to accomplish in the spring and summer this year. In looking at the rulemaking calendar, the regulation writers will be busy in the fall working with the Centers for Medicare and Medicaid Services (CMS) on three regulations. One relates to meaningful use Stage 2, one is about the parent certification criteria and standards, and one addresses governance rules. The HIT Policy Committee (HITPC) will be feeding the HITSC their use cases from its Meaningful Use Workgroup and its President's Council of Advisors on Science and Technology (PCAST) Report Workgroup. There will also work focused on vocabulary and code sets, and specifications to be considered around quality measures. This work will be intense, and the ONC could not possibly do it without the HITSC.

HITSC Chair Jonathan Perlin noted that it is remarkable to contemplate where the group began, and the work they are doing now. People not only have electronic health care systems in place and are using the processes, but they are using these tools to improve health care outcomes.

Action Item #1: The Committee formally recognized the leadership of Dr. David Blumenthal, and the team at ONC for their dedication, their wisdom, and their intelligence in moving the field forward.

3. Review of the Agenda

Perlin announced that Jim Walker is the new Chair of the Clinical Quality Workgroup, with Karen Kmetik serving as Co-Chair.

HITSC Co-Chair John Halamka said that Blumenthal left a 90-page strategic plan, a rich document with many achievable and measurable accomplishments. The Committee knows where it is moving, it has a strategic plan and an imperative of getting to meaningful use Stage 2, and now it needs to understand the work plans for all of its Workgroups.

With regard to lessons learned, Halamka reported that he has gone through the certification process for a hospital and as an ambulatory provider, so he personally has dealt with every single detail to achieve certification for thousands of individuals. He noted that it would be helpful if the National Institute of Standards and Technology (NIST) developed a Web site and instructed potential meaningful users to upload information to this site for testing purposes. This represents an opportunity to learn and improve. Subtle changes could have made a large difference in the certification process.

Action Item #2: The minutes of the last HITSC meeting, held on February 16, 2011, were approved by consensus.

4. Timeline and Milestones: Certification and Standards NPRM Stage 2 – Project Plan Discussion

ONC's Doug Fridsma said he would like to provide some situational awareness about timelines, and then drill down and offer some principles to think about regarding how to set up standards and certification processes. He hoped to receive some directional recommendations from the Committee. He discussed the milestones and timeline for the notice of proposed rulemaking (NPRM). In the third quarter of 2011, the NPRM will be drafted, and it will be published at start of 2011's fourth quarter. The NPRM must be drafted and put through review and then regulatory clearance before it is published.

He brought up several core themes for discussion. First, he discussed pragmatic vocabulary. They can borrow from other industries for security and other areas, but for health-care specific issues, the ONC needs to do the work itself, and have a pragmatic approach. Also, he offered a reminder of the lesson learned that, for vendors, "or" means "and." This means that having multiple ways of doing the same thing introduces complexity for vendors. They need to reduce alternatives in vocabulary, and drive to those vocabularies that are going to be most useful in the future.

They must also be pragmatic about the kinds of things they want people to share. SNOMED covers everything—but maybe a subset of that vocabulary would make these challenges scalable, while including the necessary vocabularies to get work done around lab reporting, care transitions, etc. Upgrading from paper to electronic transmission means reducing alternatives and increasing specificity for the sake of robust interoperability. The areas of laboratory, individual engagement, and public health are going to be important in upgrading to electronic transitions,

and the focus needs to be on care transitions. Finally, the Nationwide Health Information Network (NHIN) specifications need to be updated in the areas of content and transport standards for meaningful use.

They must constrain for success by: (1) converging to a single vocabulary for a particular purpose; (2) focus on ambulatory domain, quality reporting, and public health; (3) focusing on interoperability only, not internal representation; (4) working to address 95% of the most commonly used elements and certifying on that 95% subset; and (5) certifying on the ability to consume data where electronic health records (EHRs) do not understand the code

Discussion

- David McCallie acknowledged the desire to identify the 95% subset because the vocabularies in their native states are so large and asked what can be done to facilitate usability. For example, he was using the SNOMED core subset recently, which includes approximately 6,000 elements that have been identified as the most frequently used. However, there are many rare but important real-world diseases that are not in that subset. What can be done about that long tail of items that are critical in health care but rare in everyday use?
- McCallie also acknowledged that identifying subsets makes sense from a usability point of view, but he urged that the Committee and ONC not exclude the ability to add those less common choices, even if it means dropping into an alternative interface to do so.
- Wes Rishel said that if there is a situation where someone wants to describe a lab result with more precision than the receiver wants to receive it, it should be handled in a way that does not reduce the fidelity of the transmission. It is a shame to lose information in getting to the smaller, transmitted subset.
- With regard to care transitions, Jim Walker said that he thinks they are referring to transitions between care processes that are currently isolated. This is an important distinction, because already there are starting to be community-wide shared care processes, and he thinks it likely that the critical transitions within those integrated processes will have different characteristics and pose different problems than where the Committee and the ONC are currently focusing.
- Walker expressed his belief that they will need to use the same vocabularies internally as they do externally. Providers cannot afford to keep translating; if there are vocabularies that are not usable to manage the care processes internally, then they will also have no way to communicate with one another and share learning processes.
- Nancy Orvis works with a very large institution, and with regard to interoperability work, they identified the top 75% of interchanges between applications. Their goal was to make sure they had data standards for each of those. This group has 62 clinical specialties, and their system allows each specialty to create templates for their top 25 problem list. It is important to analyze what an organization does, and determine the institution's volume of exchanges. What is the volume of incoming and outgoing consults? Lessons learned from

the federal health architecture would be helpful to share with state health information exchanges (HIEs). At the other extreme, Orvis said, her own set of family doctors is in a very small practice. They are going to have to take a pragmatic approach: “If it isn’t on the list, fax it.” Finally, she suggested that they take the RXNorm list and make that the default norm, to avoid confusion.

- Cris Ross noted that it is not in anyone’s interest to constrain business processes, but there may be some core areas that are safety related. Medical and lab information that relates to patient safety issues is an example.
- Ross also reminded the group that determining terminologies is insufficient for some of the data they are discussing. Most lab data can be sent with a LOINC code, but value codes must be linked to a model, and without that interoperability is lost. Code fields and standards are needed, but one must go far beyond the simple exchange model to get to interoperability. Context is needed, including CDA templates, implementation guides, and detailed clinical models. These details are not specified by the standards currently.
- McCallie pointed out that there is an important distinction between reducing optionality and reducing specificity. Medicine needs to be very specific.

Fridsma then continued with his presentation, outlining the core specifications needed in the following areas: (1) directed exchange bundle, (2) lab results, (3) public health (ELR, VXU/Q/R, reportable conditions), (4) transitions of care, (5) medications, and (6) include the individual (publish to PCHR as core transition). Discussion is needed on “low regret” standards for future information exchange needs to support innovation and a learning health care system. They need to make sure the standards will not box them into a corner that will make it hard to get to new ways to exchange that they have not at this point even considered. Candidates include the following:

- Synchronous secure transport (e.g., SOAP + TLS + WS-Security and HTTP + TLS + OAuth2).
- Subset of current NWHIN specifications for exchange.
- Metadata for a universal exchange language derived from existing exchange standards.
- Distributed queries to support risk adjustment, quality reporting, public health.

Discussion

- David McCallie noted that there are reports of creating an independent foundation to manage the existing Connect software. What’s the message to those trying to implement HIE? Should they wait for this to get settled? Should they go with Connect, although it might be simplified radically?

- Doug Fridsma noted that the Committee would be discussing the Connect issue later in the meeting. They also are still waiting for the PCAST Workgroup to provide some recommendations. The responsibility of this committee, and ONC, is to establish the definition of interoperability. Connect is an important tool, but the strategy is not that everybody uses exactly the same code base. The appropriate role for the ONC is to establish clear and unambiguous standards and clear specifications, and to test those specifications.
- It was suggested that it would be useful to separate out where one model makes more sense than another.
- Nancy Orvis reminded the group that there are still connectivity issues associated with rural care, so being able to send simple messages with attachments is still relevant.

5. Direct Project Live Implementations Final Review

ONC's Arien Malec reviewed what Direct is and why it is important, and then discussed several examples of live implementation:

- Hennepin County (MN) Medical Center is sending immunization information to the MN Department of Health.
- MedAllies, a health information service provider (HISP), is delivering clinical information across transition of care settings in a "push" fashion that supports existing clinical workflows in the Hudson Valley of New York.
- Rhode Island Quality Institute (RIQI) has a Direct Project pilot that demonstrates simple, direct provider-to-provider data exchange between primary care providers and specialists as a component of Stage 1 meaningful use. They are also leveraging Direct Project messaging as a means to feed clinical information from practice-based EHRs to the statewide HIE, integrating patient data across provider settings and during transitions of care
- Secure Exchange Solutions, Inc., is conducting a secure messaging proof of concept project with selected primary and specialty care clinics and specialists in Maryland and the District of Columbia.
- Dominion Medical Associates in Richmond, VA, has traditionally been a paper-based practice but is in the process of moving toward use of an EMR. As part of this process, CenVaNet and MedVirginia are working with the practice to help it achieve recognition as a Level 3 NCQA Patient Centered Medical Home (PCMH).
- Heartland Health is an integrated health delivery system in a 21-county area of northwest Missouri, northeast Kansas, and southeast Nebraska. Partnering with the Lewis and Clark Information Exchange (LACIE), Heartland Health is using the Direct Project to replace traditional fax and phone methods.

The examples show a range of information technology providers and organizations supporting some of the largest and some of the smallest facilities in the country. A wide set of EHRs are being used in the projects, including big names and regional providers, and a range of non-EHR technology providers.

Malec summarized by saying that this is a huge stepping stone for providers, starting from the basic all the way to high clinical workflow, allowing for robust interoperability and a high degree of clinical workflow and integration. The point is, they can't stop at the simplest forms of exchange. They must make sure that their model scales from the simplest to the most robust forms.

One of the realities of upgrading the ecosystem of information exchange and connecting that to quality of care is that it takes time. Some technology providers have business and technical models that allow them to roll out Direct very quickly; for some it is much more complicated. Through the rest of 2011 a number of systems will upgrade at different times with different capabilities. Also, as with information exchange generally, success will depend on how well it gets integrated into workflow.

Malec recognized Wes Rishel and Dave McCallie as the “godfathers” of Direct.

Discussion

- Wes Rishel guessed that his doctor, a rural family practitioner, would need to get his cloud-based EHR vendor to offer the exchange. Malec agreed. Rishel then asked if Malec sees any problem with the Committee recommending that Direct be a requirement for meaningful use Stage 2. Malec noted that much of the Stage 1 and 2 meaningful use measures around directed exchange could be met by Direct. He said that Direct should not be the destination, but it is up to the Committee whether it is an appropriate step in the journey.
- In response to a question from Dixie Baker, Malec said that the “compatibility document” is now close to being finished. The concept is similar to the telephone in that there may be different standards for mobile and land telephony, but they are not called telephones if they cannot call each other. The message is that it is not called “Direct” unless it can get a message from point A to point B.
- McCallie asked whether there should be a test server, or a “ping” server for Direct, so that people can verify that they pass a common test server. It could be hosted by ONC, NIST, or even a private entity. Malec said that has been discussed. In the absence of it being a certification criteria, they would need to look at hosting it internally. It would be fairly inexpensive, and would be very useful. McCallie suggested that it might be a business opportunity for someone.

Next, Fridsma updated the Committee on NW-HIN Exchange. There are currently 10 Exchange participants, and there are 9 more applicants that are Beacon Communities, state HIEs, CMS, and partners. There will be a tripling of users in the next year. Fourteen additional inquiries have come in, and their constraint is that organizations must have a contractual relationship to the

government. The ONC has been working on establishing governance, per the HITECH requirement that ONC establish a governance mechanism for NHIN.

This governance work is important because it is necessary for the Exchange to grow beyond those entities tied to federal contracts, grants, or cooperative agreements. Also, states are establishing governance roles in the absence of national governance. Fridsma presented the recommendations of the Governance Workgroup:

- Principles for governance.
- The federal government should support and provide strong incentives to vigorously promote adoption.
- There should be shared governance responsibilities.
- There should be conditions for trust and interoperability and a mechanism to verify that these conditions are satisfied.
- ONC should oversee NW-HIN governance and assure accountability.

Next Fridsma updated the Committee on the Connect project. Connect developers are expanding, with Mitre creating a shared development environment. Emphasis is being placed on short-term priorities and longer-term testing strategies, and two new technical leads have been hired. He shared the release cycle and development dates, and said that a new development contract is expected to be awarded within the next month. Also, they are building an automated test environment for testing Connect installations using NHIN standards.

He also explained that the Alembic Foundation, a non-profit started by two former Connect team members, is using Connect 3.1 as their baseline for future development. Their next release may diverge from the Connect code base. Their product, Aurion, does not replace Connect. If Connect and Aurion both properly implement the NHIN standards and specifications, then they should be interoperable.

Discussion

- In response to a question by David McCallie regarding to whom the governance rules will apply, Fridsma said that the rules are intended to be voluntary. They are still working out whether this is a brand or a criteria that one can say they have met in order to be able to exchange. Jodi Daniel said that they are working on drafting a proposed rule, so there is no answer yet. They are looking at what services to include, and not just governance of the Exchange project. The statutory language refers to rules guidance exchange, not just one particular project. This is the most challenging item that they are still trying to define, she said.
- Jamie Ferguson noted that a desire has been expressed to get the government out of the software development business. With the hiring of new developers, is that a change in

direction? Doug Fridsma indicated that it is not. The money for the Connect re-compete comes from resources that they have been entrusted with in terms of managing the support of federal government partners. There needs to be an orderly transition to support getting back to ONC's core mission around testing and developing high-quality specifications, and they must be sensitive to partners who are invested in these tools right now.

- Cris Ross acknowledged that he may have a conflict of interest because his organization is involved in the commercialization of exchange outside these projects. He said that there should not be a strong rule around something that is considered federal technologies. It will create a much cleaner and easier to understand marketplace if the rule includes all of the methods of transport. He wanted to underline that, in part because organizations like his sometimes get accused of trying to do things in a propriety fashion. It is better to operate within a set of rules that is governed in a consistent fashion.

6. Clinical Quality Workgroup Update

Jon Halamka announced that Jim Walker has agreed to assume the chairmanship of the Clinical Quality Workgroup, with Karen Kmetik as Co-Chair.

Jim Walker noted that the Workgroup has not met yet. They are hoping to include a representative from long-term post-acute care for the Workgroup. Their first meeting will be on April 7, followed by another meeting on April 18.

Walker said that Floyd Eisenberg reviewed the Quality Data model for himself and for Karen Kmetik.

7. Privacy and Security Standards Workgroup Recommendations

With regard to work sequencing, Halamka said that successful Workgroups have devoted calendar months to particular topics. He suggested they publish a calendar with the four or five critical topics that they want to think about, because they will need to have covered a whole list of topics by the end of the year in order to align with ONC activities.

He then introduced Privacy and Security Workgroup Chair Dixie Baker. Baker reported that Healthcare Information and Management Systems Society (HIMSS) Senior Advisor for Privacy and Security Lisa Gallagher has joined the Workgroup. The group's role is changing from creating the detailed specifications of standards to simply defining the requirements that those standards must meet. The job of writing the actual specifications will now fall to the Standards and Interoperability (S&I) framework.

The Workgroup has been given two standards for which to specify requirements: digital certifications and enterprise-level provider directories (ELPDs).

Following a brief tutorial about digital certificates, Baker reviewed the Workgroup's recommendations for requirements and evaluation criteria for a digital certificate standard.

Regarding the management of trust anchors, David McCallie said that the reason PKI-based models for secure messaging failed in the past is that it is too complicated to make decisions about managing trust anchors. The Direct model is to use health information service providers (HISPs). Somebody needs to make these decisions, but the individual user trusts the issuer to do so. On a PC, the vendor builds into the browser pack a list of certificates that one's browser would trust.

Baker then reviewed the second recommendation, which is the need for investigation of alternatives for cross-certifying digital certificate issuers with federal bridge certificate authority (CA).

Discussion

- Wes Rishel asked if a CA is allowed to cross-certify with the federal government, and that CA issues a certificate to Alice, then from that point do federal agencies trust Alice the same as if she had a certificate issued from the federal bridge? Baker explained that a certificate would indicate what Alice had to provide in order to receive that certificate. The federal government will trust the certificate to have been capable of being used in exchanges with the federal government, but different places may require different levels of identity validation. The certificate is trusted, but only at the level of identity that it was issued.
- Rishel then asked whether that implies that the requirements to become a cross-certifying CA and maintain that status are fairly strong. To what extent does cross-certifying with the federal government narrow down the market for certificate authorities? Baker said that this is what they are asking the ONC to review. They do not know what the cost is, and that is something ONC will hopefully investigate.
- Jim Walker offered a friendly amendment: that the ONC also be asked to estimate the financial benefits.
- Nancy Orvis noted that it would benefit many if the exchange could be between a number of providers, not just federal agencies.

Baker presented the last series of issues and questions around CAs who issue certificates for use in health exchanges, such as Direct:

- Defining a mechanism for establishing the legitimacy and trustworthiness of a certificate authority.
- Defining a minimum level of trustworthiness for CAs issuing certificates for Direct exchanges, for example:
 - Is certification by WebTrust or ETSI sufficient for health information exchange?
 - Does the CA need to meet the minimum standard defined for a trusted relationship with the Federal Bridge CA?

Action Item # 3: The Committee approved the three Privacy and Security Workgroup recommendations relating to digital certificates, and will pass along to the Policy Committee the workgroup's questions and the tutorial on digital certificates.

Privacy and Security Workgroup Co-Chair Walter Suarez reviewed the Workgroup's recommendations regarding entity-level provider directories (ELPDs), which were previously discussed and approved by the HITPC.

Discussion

- One Committee member asked whether there is a presupposition that any registry participant would have to offer at least one type of information services in order to participate? Or might there be people who are not participating in one of the services? Suarez said that this is a policy question as to whether the entities that do not support a specific type of exchange could be listed in the directory or not. His expectation is that any organization involved in the exchange of health information could expect to be listed. If they do not have an electronic capability to exchange information, they would not expect to be listed because they don't have that capability.
- Jon Halamka noted that they do not have 100% adoption of EHRs, but there is 100% adoption of faxing. They could have an ELPD that can list a well-formed URI of some variety, a secure e-mail address, or a fax number. They can argue about whether or not faxes are safe, reliable, and secure, but until there is 100% EHR adoption, having a directory that lists fax numbers may not be a bad thing.
- Suarez said that one of the purposes of the concept of ELPD was to support electronic exchanges and support Direct and other methods of electronic exchanges. It did not preclude the possibility of expansion to more of a "Yellow Pages" kind of directory that includes basic information about how to communicate in a non-electronic way. However, the main purpose of the ELPD was to support electronic exchange. Suarez will raise this topic for discussion by the HITPC's Provider Directory Workgroup.
- Nancy Orvis asked whether there is any relationship between the national provider taxonomy and what will be provided in this directory. Suarez said that the National Provider Identifier (NPI) could be seen as one of several sources for this type of information. Orvis said that one of the issues with the national provider database is that there is no enforcement of syntax over how people's names are listed. This might be an opportunity clean up some of these syntax issues.

Suarez then presented an illustration of the ELPD model to show what the HITPC was describing, and another illustration showing the standards requirements. He also presented the standards requirements for which this Workgroup needs to develop recommendations, and the Workgroup's progress to date.

Discussion

- Jon Halamka explained that it makes sense to have a common set of standards to be used across ELPDs and ILPDs, and those will be presented in May. Arien Malec expressed concern about waiting until May because of getting things into the NPRM.
- Wes Rishel cautioned against exclusion by omission, in that one of the presentation slides (slide 27) called for electronic exchange between the EHR and registry, while another slide (slide 26) implied that this is the means of operation for everyone accessing the registry. It may be there are Web-based ways for users to use the directory, rather than through an intermediate system. Possibly there is no need for a standard, but he wants to make sure they are not excluding that business model.
- Marc Overhage asked whether the model is going to describe the requirements, and then stack up options against those requirements. Suarez affirmed this. Overhage said that this is a good example of where they will want to not focus too hard on standards, but keep the emphasis on progress.
- Halamka offered an example of how they could manage this in meaningful use Stage 2. In Massachusetts, they have created a directory, but it is not going to be useful to anyone outside the area. It would probably be trivial to retrofit it, though, and they could do a demonstration. He said that he hopes they come out with a set of recommendations so that they do not end up with more than 50 different HIEs creating more than 50 different front ends for their directories.
- Baker said that what they would want for meaningful use Stage 2 is simply to be able to query the directory. Malec said that states are looking for direction involving all aspects of the project. With respect to EHR certification, the much narrower focus of query retrieve is all that is needed.
- McCallie suggested that it would be helpful if the discoverability of certificates could be piggybacked in some way with directories. It would not make sense to build two separate models that accomplish essentially the same thing: one is the name on the certificate, the other is the key to the certificate.

8. Clinical Operations Workgroup Update

Clinical Operations Workgroup Chair Jamie Ferguson offered a summary of a hearing on devices that was held on the day before this HITSC meeting. A full eight hours of panel presentations and discussions covered a broad set of issues relating to the possible inclusion of device-related measures and standards in meaningful use Stage 2 or 3.

He discussed some of the themes that Workgroup members heard. For example, consumers and patients need device interoperability to be made cheap and easy for compliance and to achieve improved outcomes. Home monitoring devices for diabetes was one example. The biggest problem is last-mile connectivity and the setup of remote devices to connect to wherever they

need to connect. Several different approaches for in-home setup were discussed, with no clear consensus for solutions to that barrier.

The Workgroup heard that middleware and data intermediaries will be around for the foreseeable future. Some argued for the necessity of direct plug-and-play between devices and EHR. However, most said that intermediaries are a necessary evil, and there is no way around that for in the near term.

They heard about problems and benefits from the perspective of providers seeking meaningful use incentives. There are issues around updating device security without adequate assurance on the provider side of the patient safety approval of those updates, although the U.S. Food and Drug Administration (FDA) was present and indicated that although it is the manufacturer's responsibility, the provider can apply the patches. That means the provider is taking on that manufacturer's responsibility.

There is non-standard vocabulary being used, and also no standard technology on the EHR side to receive and hold device source data.

There is a whole set of problems around payments and incentives: sometimes there is no reimbursement for device use. In fact, seven different panelists cited business model concerns as reasons for the lack of standardized interoperability. The HITSC was asked to align incentives with improvements of outcome that can come from devices with an EHR in coordinated care. They were also asked to seek reimbursement for tele-health.

Strong evidence was presented showing that providers are having problems getting all of the data from devices. Manufacturers typically set up devices so that only a subset of data can be provided to an EHR, but providers want all of the data all of the time.

Finally, assuring that the remote patient identity is correct was perhaps the top problem for remote devices. Patient ID and correlation back to the provider setting was the top issue for remote devices.

Great benefits were also discussed at the hearing. For example, devices offer a lot of value for the partnership of the care team, and the partnership with the patient is strengthened. There is a great improvement of outcomes, lower readmission and admission rates—a lot of dramatic benefits can come from the use of home monitoring devices in particular.

A number of EHR vendors and the EHR Vendor Association indicated that vendors are not focused on establishing end-to-end interoperability with all devices, but rather interoperability to and from the data intermediaries. This is the Integrating the Healthcare Enterprise Patient Care Device (IHE PCD) approach of ensuring that the data can be sent back to the EHR from the intermediary, but leaving the device-to-intermediary communication for the marketplace to solve. A few consumer-oriented devices do have end-to-end interoperability relatively well assured through the Continua specification for consumer-oriented devices. On the other hand, there are concerns about a vendor-run certification process as opposed to the neutral approach that we have for EHR certification.

The Workgroup plans to convene to consider this input. They expect to consider recommendations for meaningful use Stage 3. They heard that Stage 2 is too premature. However, while it may be possible to identify a few use cases, there was a strong sense that it would be desirable to set the direction for those standards in Stage 2, even though the requirement would not be until Stage 3, to give the marketplace adequate time to prepare for Stage 3.

Discussion

- Liz Johnson noted that it is clear that the value of the data from the biomedical devices is desirable and that if there is going to be care across the continuum it must happen, but they are not ready now.
- Halamka said he has a wi-fi based electronic bathroom scale at home. When he steps on it, it does a restful exchange to an intermediary site provided by manufacturer, which provides a desktop dashboard that allows Halamka to forward his weight information to his PHR and a whole host of other sources. This is a Web-based interface giving him a choice about where to send his data. The last-mile issue for this device was whether or not one has a wi-fi access point in the house. If the company goes out of business, though, the device will be useless.
- Jamie Ferguson acknowledged the complete range of devices, and said it was a very broad discussion. People had to switch gears throughout the day; some of the devices being discussed were in the class like Halamka's bathroom scale, but most of the discussion was about the more traditionally regulated class 2/3 devices.
- Wes Rishel said that one additional takeaway about patient ID was that there was extreme concern that it not be done in the middle layer, but rather in the instrument. Issues related to patients in transport are an area that they will need a long lead time to address. The notion that there could be some standard of getting patient ID into an instrument and could then be in the data stream was very concerning to a number of people.
- Rishel also said that there is a conflict between two requirements that they have heard about: (1) providers want all the data, and (2) standards. The more complex the information, the less likely it is to be standardized. They need to look at standardizing what will go into the EHR, rather than the full set of data.
- Medical Device Data Systems (MDDSs) are intermediaries, some of which only transmit data, while others aggregate, normalize, and do other functions. Wes Rishel said that the ones that compress, take the best reading, or anything similar, will come into substantially more enforcement under the FDA in 2017, including such systems underwritten by hospitals.
- Ferguson said that one of the things that came up during the FDA portion of the hearing concerns the unique device identification proposed rule that they are working on. Any hospital or clinician's office that configures an interface may be considered a manufacturer of that intermediary device. This means they have to have the ability to generate a structured label and register it in the FDA database, and for an implementer that could become

significant. This might become an issue in the penalty phase of meaningful use, because their lead time is probably longer than the incentive period.

- Stan Huff said that one of the things that struck him is that there have been adequate standards in the past that were not adopted. They need to focus on why that is and how to change the motivation to make it successful. Intermountain Healthcare implemented IEEE1073, and it went well, but it was not widely adopted because there was no financial incentive for manufacturers to adhere to that standard. They must be careful to provide a business case and a motivation to use them.
- Also, Huff repeated a useful clarification that Wes Rishel made on the day prior to this meeting, related to the notion that intermediaries are necessary. Those functions need to be performed, but the intermediary could be in the EHR or in the device itself. They are not mandating an independent company to be the intermediary.
- Jonathan Perlin noted the breadth of the ecosystem of devices and the lack of continuity. He pointed out the stunning statistic that the average American is on track for radiation exposure that is on the same level as Hiroshima. There is no aggregating method for tracking cumulative radiation exposure.

9. Implementation Workgroup

Implementation Workgroup Co-Chair Judy Murphy explained that this Workgroup is at a turning point. They are now focusing their attention on the certification process. The Workgroup is revising its membership and creating a work plan for the next 9 months. That plan will consist of a current assessment of the certification of testing scripts, and developing a future state recommendation for this. The work will probably consist of surveying and getting input from the general public, and possibly a hearing this summer.

Workgroup Co-Chair Liz Johnson indicated that the group wants to take advantage of the learning from meaningful use Stage 1, and start looking at Stage 2.

Discussion

Jon Halamka mentioned a conversation he had with Farzad Mostashari, in which Mostashari described a certification process as a linked sequence of testing. Enter a patient. Enter an order. As part of an order there is a drug interaction. The data enters into a registry, where a quality measure results. This would be one process rather than perhaps 27 unrelated tests.

10. Public Comment

- Carol Bickford of the American Nursing Association noted that the Clinical Quality Workgroup is glaringly missing some registered nursing participation, in conjunction with long-term care representation. Regarding slide 27 in the Privacy and Security Workgroup presentation, based on the discussion about National Provider Identifier (NPI) integrity of

data, there must be some standard around the ELPD registry system having to do with the development of structure and content and registry submission.

- Robin Raiford from AllScripts said she has reviewed the 113 National Quality Forum measures in detail to try to find a common thread for meaningful use Stage 2 and Stage 3. She explained that if one pulls out diagnoses, meds, labs, and results, there are 15 concept categories that include approximately 342 concepts. There are 2,600 unique descriptors, which is daunting, and points to Carol Bickford's comment about including nursing representation. There are 114 ways to describe tobacco use, 88 ways to describe a cough, etc. She would not want to be the nurse who has to slide open a gigantic list to describe a particular condition. They will start to see people trending, using the first four or five items on the drop-down list. They are getting close to the line of questioning that a patient will tolerate. Exclusions are also an issue: there are 63 coded reasons why a practitioner might not do something.
- Gary Dickinson, representing CentriHealth, addressed Doug Fridsma's remarks distinguishing interoperability from internal representation of data. He said that the clinician needs to be able to say, "This is what I saw on my screen and this is what I accepted." As the information gets translated through an intermediary, who knows what that it will end up looking like? That end-to-end continuum gets to the issue of author repudiation. Interoperability needs to be looked at not as point-to-point, but ultimately as end-to-end. What did it start out like, what did it end up like? Also, at a HIMSS conference last month, he discovered a number of systems claiming to be EHRs. He noted that when this Committee came in, the previous certification process went away, and the new set of criteria is significantly lower than what would have been required in 2009 by ONC-promulgated materials. Dickinson characterized this as a disservice to the community.

"We have well-established standards in place for EHR System functionality. ISO/HL7 10781 EHR System Functional Model Release 1.1 was published in November 2009. (EHRS FM Release 2 started initial ballot last week.) This International Standard describes core functionality and is available for reference by the HITSC.

As an industry, we also have a mature EHR System certification program. We identified core (baseline) functionality as certification ramped up from 2005-2009. We created a progressive roadmap outlining future objectives for functionality certification. While core EHR system functionality remains vital it is substantially missing in 2011 MU criteria.

While gaps are evident, disjunction in promoting well-established benchmarks for core (baseline) EHR system functionality substantially increases the risk of failure."

SUMMARY OF ACTION ITEMS:

Action Item #1: The Committee formally recognized the leadership of Dr. David Blumenthal, and the team at ONC for their dedication, their wisdom, and their intelligence in moving the field forward.

Action Item #2: The minutes of the last HITSC meeting, held on February 16, 2011, were approved by consensus.

Action Item # 3: The Committee approved the three Privacy and Security Workgroup recommendations relating to digital certificates, and will pass along to the Policy Committee the workgroup's questions and the tutorial on digital certificates.